

Structured Product Labeling (SPL) OTC Sub-team Teleconference

Monday, November 24, 2008, 1:00 pm – 2:30 pm ET

Minutes

I. Welcome and Introductions - call and/or presentation participants (listed alphabetically):

- Mark Bayer, Reed Technology and Information Services, Inc. (presenter)
- Cheryl Blik, Teva Pharmaceuticals USA
- David Brown, Colgate Palmolive Company
- Terry Brunone, GlaxoSmithKline (SPL Process Team co-leader)
- Shelia Dy Juanco, Medline Industries, Inc.
- Douglas Flint, Reckitt Benckiser, Inc.
- Chris Guay, The Procter & Gamble Company
- Maureen Kapustynski, Cadbury
- Mike Koenig, U.S. Food and Drug Administration
- John Lorenc, Reed Technology and Information Services, Inc.
- Paula Market, GlaxoSmithKline Consumer Healthcare (co-leader)
- Kathryn Moreng, Bayer Consumer HealthCare
- Peggy Nolder, *company unknown* (guest)
- Jeff Poisson, i4i
- Eva Rivera, Glemser Technologies Corporation
- Gary Saner, Reed Technology and Information Services, Inc.
- Howard Shatz, Data Conversion Laboratory
- Beth Thompson, Medline Industries, Inc.
- Craig Trautman, Intagras
- Marcia Howard, CHPA staff (sub-team liaison)

II. Standing Teleconference Date and Time

The next three teleconferences will be December 8 and 15, 2008, and January 12, 2009, at 1:00 pm ET (and ending around 2:30 pm). Note: The December 22nd call has been re-scheduled for December 15th.

III. FDA Submission

The submission, based on the October 23, 2008, [*Federal Register*](#) notice, will be finalized and submitted by the end of the day. [Completed November 24, 2008]
Thanks to everyone for their feedback, input, and assistance in developing a quality document. The final submission will be available on the CHPA website as well as directly from SPL OTC sub-team members.

IV. Vendor Presentations

The first vendor presentation will be held today and will feature Reed Technology and Information Services, Inc. Other vendor presentations will be scheduled as soon as possible. Presentation dates were determined by order of response and availability. The current schedule is as follows:

Vendor Presentations:

- ◆ December 8, 2008: Quark, Inc. (confirmed)
- ◆ December 15, 2008: Intagras (confirmed)
- ◆ January 12, 2009: i4i (confirmed)
- ◆ January 26, 2009: Glemser Technologies Corporation (tentative)
- ◆ February 9 *or* 23, 2009: Data Conversion Laboratory (tentative)

The vendor presentations are provided as educational opportunities only and are ***not*** intended to be an endorsement or recommendation for any specific product and/or

service. **Any vendor interested in making a presentation to the sub-team should contact Marcia Howard via email if they haven't already done so.**

FDA sub-team members cannot be present for the vendor presentations, so routine business will be conducted during the first part of the bimonthly calls followed by the vendor presentations. Call-information will be sent via **WebEx** so please watch for the messages in your inbox. To the extent possible, companies are asked to view the presentations from one computer as a cost-savings measure.

V. Educational Opportunities

No educational opportunities were announced.

VI. Other

A. Participation on the SPL OTC sub-team

Anyone who is interested in joining the sub-team should contact Marcia Howard to be added to the roster.

B. FDA Pilot Program

Companies are encouraged to participate in FDA's Pilot Program for electronic submissions to the extent possible. OTC submissions must be completed electronically on and after June 1, 2009, but early transitions from paper to electronic submission are encouraged. Note that once a submission has been made through the Pilot Program, all future submissions for that instance must continue to be made electronically. Guidance documents are available at the agency's website.

MDH/11-25-08

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Last Revised: November 25, 2008 Sent: November 25, 2008